DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

October 18, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUEST
Kevin Ruda, President
Bear Creek Country Kitchens, LLC
325 West 600 South
Heber City, Utah 84032-2230

Ref#: Den-05-01

Dear Mr. Ruda:

The Food and Drug Administration (FDA) collected samples of some of your products, including Cheddar Broccoli Soup Mix, on May 5, 2004, during a visit to your manufacturing facility. The samples were collected to determine your firm's compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and its implementing regulations in Title 21, Code of Federal Regulations. We previously collected samples of your Cheddar Broccoli Soup Mix from your facility on May 22, 2003. You can find the Act and regulations on FDA's web site at www.fda.gov.

Our analysis of the Cheddar Broccoli Soup Mix, code B1412604 PLS, collected during the May 2004 inspection found that the product is misbranded under section 403 (a) (1) of the Act in that the labeling is false or misleading because the amount of Vitamin C present is less than 80 percent of the amount declared (see 21 CFR 101.9 (g) (4) (ii)). The label declares that the product provides 35% of the Daily Value (DV) of Vitamin C per serving; however, our analysis found the Vitamin C content to be 20.6% (original analysis) and 36.3% (check analysis) of the value declared in the nutrition information on the label. These findings were similar to the results of our analysis for a sample of your Cheddar Broccoli Soup Mix collected in 2003.

This letter does not represent a comprehensive review of all of the products distributed by your firm, nor does it represent a complete review of all product labeling and nutrient content. You must ensure all products distributed by your firm comply with the Act and its implementing regulations. Failure to make prompt corrections may result in further enforcement action being initiated by the Food and Drug Administration. This could include seizure of illegal products and/or injunction against your firm.

Please respond to this office in writing within 15 working days of receipt of this letter. Your response should outline the specific things you are doing to correct this deviation and to prevent its recurrence. If you cannot complete all corrections before you respond, please state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Compliance Officer Shelly L. Maifarth at the address indicated in the letterhead. She may be reached at (303) 236-3046.

Sincerely,

B. Belinda Collins
District Director